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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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10/776,330

02/12/2004

Jean-Luc Galzi

0508-1053-1

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7590

06/09/2006

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EXAMINER

JOIKE, MICHELE K

ART UNIT

PAPER NUMBER

1636

DATE MAILED: 06/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|-------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/776,330 | GALZI ET AL. | |
| | Examiner | Art Unit | |
| | Michele K. Joike, Ph.D. | 1636 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) 11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 12-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 09/445,205.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>2/12/04</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election of Group I in the reply filed on April 21, 2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 1-10 and 12-16 are examined. Claim 11 is withdrawn from consideration as being drawn to a nonelected invention.

Priority

Applicant is advised of possible benefits under 35 U.S.C. 119(a)-(d), wherein an application for patent filed in the United States may be entitled to the benefit of the filing date of a prior application filed in a foreign country.

Receipt is acknowledged of French application 97/06977 filed on June 5, 1997 and submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file. It is noted that no English translation has been filed.

Claim Objections

Claims 1, 10, 12, 15 and 16 use the term "quantic" for fluorescent yield, however "quantum" is the more acceptable term.

Claim 8 is objected to because of the following informalities: In claim 8, the genus names need to be capitalized. Also, there needs to be an "of" inserted between "consisting" and "CHO cells" in line 4. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 12-14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant claims a kit with buffers and media required for the energy transfer between a protein and a ligand. The claims read on a broad genus of buffers and media.

The written description requirement for a genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice or by disclosure of relevant identifying characteristics, i.e. structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show applicants were in possession of the claimed invention. In the instant case, the specification does not sufficiently describe a representative number of buffers and media by actual reduction to practice or by disclosure of relevant identifying characteristics.

Although the specification mentions buffers and media, it does not delineate which buffers and media would be required for an energy transfer. The skilled artisan cannot envision a sufficient number of embodiments of the instant invention from the instant specification because the specification only discloses the general category of buffers and media, and does not suggest any particular buffer(s) or media to be used. Not all buffers or media will work with the claimed invention. As a result, the skilled artisan would not be able to envision the claimed invention. Therefore applicant has not satisfied the written description requirement to show the skilled artisan that they were in possession of the claimed genus.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-10, 12-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 10 and 16 claim cell fragments. It is unclear how fragments of cells can function in this invention, for example, how a cell fragment can express a fluorescent protein fused with a nucleic acid encoding a target protein.

Claims 1, 10 and 12-16 are vague because Applicants recite that the fluorescent protein is GFP, and then recite that the light is emitted by the fluorescent protein or "a fluorescent substance." Where does the fluorescent substance come from?

Claim 1 has the language "selected from the group consisting of green fluorescent protein". There is no group. Similarly, claims 12 and 15 have the language "this protein being further chosen from green fluorescent protein". It is unclear how a protein can be chosen from another protein. Examiner is interpreting the fluorescent protein as being GFP or a fluorescent protein that is a derivative of GFP for examination purposes.

Claim 2 recites the limitation "the G protein" in line 4. There is insufficient antecedent basis for this limitation in the claim. It also recites the limitation "the insulin receptor" in line 6. There is insufficient antecedent basis for this limitation in the claim. It also recites the limitation "the steroid receptor" in line 9. There is insufficient antecedent basis for this limitation in the claim.

Claim 2 is also vague because it is unclear to what "steroid receptor" applicants are referring. Different steroids have different receptors. This also applies to "the G protein", there are hundreds of different G proteins. Which one are applicants referring to?

Claims 3 and 4 indicate that the labeled substance is Bodipy or coumarin. However, Bodipy and coumarin are used to label substances. For example, in the specification in example 4, Bodipy is used to label neurokinin A.

Claim 5 has the fluorescent protein fused to the N-terminal side and the target protein fused to the C-terminal side. Claim 6 has the fluorescent protein fused to the C-terminal side and the target protein fused to the N-terminal side. However, it is not disclosed to what the proteins are fused.

Claim 9 recites the limitation "the donor" and "the acceptor" in line 4. There is insufficient antecedent basis for this limitation in the claim.

Claim 9 states that a signal can be abolished by the addition of a non-fluorescent substance of similar pharmacological specificity. There is no guidance in the specification as to what would constitute similar pharmacological specificity, so it is unclear what parameters would apply to meet the standard of similar pharmacological specificity.

Claims 12-14 limit the fluorescent protein to a GFP (claim 12) and an EYFP, EGFP or an ECFP (claims 13 and 14), but then later claim "a fluorescent protein", which can refer to any fluorescent protein, and is contradictory.

Claims 12-14 claim a kit with buffers and media required for the energy transfer between a protein and a ligand, but although the specification mentions buffers and media, it does not delineate which buffers and media would be required for an energy transfer.

Claim 13 recites the limitation "said second fluorescent protein enhanced cyan fluorescent protein" in line 8. There is insufficient antecedent basis for this limitation in the claim.

Claim 14 recites the limitation "the G protein" in line 3. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

A person shall be entitled to a patent unless –

Claims 1, 15 and 16 are rejected under 35 U.S.C. 102(a) as being anticipated by Miyawaki et al.

Applicants claim a method for detecting a protein-ligand interaction comprising cells containing a nucleic acid sequence expressing a fluorescent protein fused with a nucleic acid sequence encoding a protein. The fluorescent protein should not alter the properties of the protein, nor the interaction between the protein and the ligand. The fluorescent protein has to have an extinction coefficient of greater than 14,000 and a quantum fluorescent yield of greater than 0.38. The ligand is labeled with a molecule capable of absorbing the light emitted by the fluorescent protein. Cells are excited to detect the energy transfer, and therefore, non-covalent interactions.

Miyawaki et al (Nature 388: 882-887, 1997, specifically Abstract, pp. 882 and 886 and figure 1) teach a method for detecting a protein-ligand interaction comprising cells containing a nucleic acid sequence expressing a fluorescent protein fused with a nucleic acid sequence encoding a protein. Miyawaki et al teach a domain structure of EBFP or ECFP as the donor, calmodulin-M13 hybrid, and EGFP or EYFP as the acceptor. They also teach a construct with ECFP fused to calmodulin and M13 fused to EYFP for an intermolecular interaction. FRET is a nondestructive spectroscopic method that does

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not alter the properties of the protein, nor the interaction between the protein and the ligand. ECFP, EGFP and EYFP have an extinction coefficient of greater than 14,000 and a quantum fluorescent yield of greater than 0.38. The ligand is labeled with EYFP that acts as an acceptor capable of absorbing the light emitted by ECFP. The cells are excited to detect the energy transfer, and therefore, non-covalent interactions (figure 2).

Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

Allowable Subject Matter

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele K. Joiike, Ph.D. whose telephone number is 571-272-5915. The examiner can normally be reached on M-F, 9:00-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michele K Joike, Ph.D.
Examiner
Art Unit 1636


DAVID GUZO
PRIMARY EXAMINER